



November 10, 2008

Water Docket
Environmental Protection Agency
Mailcode: 4203M
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OW-2008-1517, Study of Unused Pharmaceuticals from Medical and Veterinary Facilities (New), EPA ICR Number 2316.01, OMB Control No. 2040-NEW

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the study of unused pharmaceuticals from medical and veterinary facilities (the study). For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

ASHP has long supported the safe handling of hazardous drugs that may present an acute or chronic hazard to patients and health care practitioners. This concern extends to the impact of pharmaceutical waste products. The Society publishes the ASHP Guidelines on Handling Hazardous Drugs, which recommends safe practices for the preparation, administration and disposal of hazardous pharmaceutical products. Pharmacists are the medication experts and, together with pharmacy technicians, these individuals play a leading role in managing the proper disposal of pharmaceutical wastes, including hazardous drugs and controlled substances.

Practical Utility of Proposed Survey

The proposed survey instrument will collect information on health care facilities' management of pharmaceutical waste during a 30-day period in 2007. While retrospective analysis could provide useful benchmark information, it has several limitations related to the collection and use of the data. Most facilities do not maintain records to the specificity defined by the survey questions. For example, it is unlikely that

facilities have recorded the number of tablets of clopidrogel disposed in a given month in 2007 (see question A-21). If the facility does not have records, the respondents are instructed to collect data on current disposal activity for a 30-day period. This is a necessary, and preferred alternative, but the impact of this distinction should be noted. Recent media attention and increased scrutiny of pharmaceutical waste disposal in some EPA districts has likely had a significant impact on practices since 2007. If dual reporting approaches are used, the EPA should also note this two-pronged approach in assessing and reporting the survey results.

ASHP strongly encourages the EPA to instruct all facilities to complete the survey by providing prospective, rather than retrospective data. Further, the duration of this prospective collection should be decreased to no more than two weeks. This approach would ensure collection of accurate data while minimizing the burden on facilities.

In the comment section on specific questions (p. 3 of this letter), the Society notes those questions that will be challenging or impossible to measure accurately on a retrospective basis. Prospective data collection would be labor-intensive for facilities but would result in enhanced data. In addition, product-specific recommendations and DEA regulations intended to prevent abuse and diversion of controlled substances frequently conflict with other regulations. Pharmacists are overwhelmed by what to focus on and confused about discrepancies between these federal programs. In addition, individual states or municipalities may impose more strict regulations.

Data from ASHP's National Survey, which assesses the role of hospital pharmacists in managing and improving the medication use process, demonstrates the need for education. In 2008, 11.4 percent of pharmacy directors surveyed indicated that they had no knowledge of RCRA requirements. While approximately 83% of respondents noted that staff in the pharmacy and patient care areas follow similar procedures for pharmaceutical waste disposal, 10.8 percent indicated that they were uncertain if disposal procedures in patient care areas mirrored the practices employed within the pharmacy.

ASHP strongly encourages the EPA to develop different surveys for the various health care settings that have been proposed for data collection for this survey. The staff involved, product storage, extent of usage, and adherence to required and recommended disposal procedures vary significantly in long-term care, hospice, physician offices, and free-standing ambulatory clinics compared to those same practices in hospitals and hospital-based clinics. For example, private oncology groups frequently employ nursing staff to prepare, administer, and dispose of drug products. By contrast, in the hospital setting, responsibility for these functions is divided among pharmacists, pharmacy technicians, and nurses. The focus of each questionnaire should take into account unique practices for the type of practice setting. For example, in the hospital setting, expired medications and partial fill vials are major contributors to pharmaceutical waste products. In long-term care settings, un-administered doses may be the predominant source of waste generation. ASHP believes that distinct questionnaires are needed to ensure that an

accurate picture of waste disposal in each setting is obtained, while still permitting an aggregation of results.

Extent of Burden on Facilities and Suggested Strategies for Implementation

While ASHP supports the survey's intended goal of identifying and improving the proper disposal of pharmaceutical waste, the burden placed on health care facilities by this process would be substantial. Facilities determine the disposal waste stream for specific drugs based on classification systems provided by National Institute of Occupational Safety and Health (NIOSH), the Environmental Protection Agency (EPA), the Drug Enforcement Agency (DEA), the Department of Transportation (DoT), and state and local regulations. These classification systems are incomplete, lack currency, and provide contradictory information. These issues impede efforts to manage pharmaceutical waste appropriately and will limit facilities' capability to answer questions accurately and complicate interpretation of survey results by the EPA. This inconsistency limits the best intentions of facilities to apply best practices to pharmaceutical waste disposal. For this reason, ASHP strongly opposes the EPA's plan to issue criminal fines or civil penalties to facilities that file late, or otherwise fail to comply with filing instructions, as described in the introduction on page *i*. This effort should focus on the collection of data for benchmarking and identification of areas for education.

To best develop a complete and accurate picture of pharmaceutical waste disposal processes, ASHP encourages the EPA to gather data through pilot studies at a smaller number of sites that represent facilities with variable characteristics (e.g., large, urban teaching facility, rural hospital, oncology center, etc). A prospective approach, rather than the retrospective one described in the proposed survey, is highly encouraged.

In part B of the survey, questions B-2 and B-3 represent an unnecessary disclosure of information (unless EPA can clarify how the collection of the facility's revenue and operating costs from 2005 through 2007 would enhance the quality or usefulness of the data). In addition, with the exception of questions B-8 and B-9, the questions for non-governmental facilities duplicate questions in Part A, Facility Information.

Specific Comments on Questionnaire

In the survey instructions, under questionnaire overview, ASHP recommends specific inclusion of pharmacists as individuals who are most knowledgeable about the requested information. In most facilities, accurate data collection will require collaboration by many individuals, including pharmacists, nurses, and other staff, such as the institution's industrial hygiene officer. For this reason, the instructions should be modified to encourage a team-based approach to completing the questionnaire. This modification will ease the burden of data collection and result in data that more accurately represents disposal practices in different areas of the surveyed facility. This approach is critical in larger facilities where disposal occurs within the pharmacy and in multiple patient-care areas.

Additionally, the Certification Statement on page *vi* should require the signature of the facility's owner, chief executive officer, or chief operating officer instead of (or, if EPA still intends to require the signature of staff, as well as) the signature(s) of staff who led completion of the survey. This will ensure that appropriate time and resources are provided to staff designated to collect and document data for the survey.

Part D of the survey defines unused pharmaceuticals as products purchased or prescribed for a patient but not used. The definition should be clarified to exclude products that are returned unused, but that can be dispensed to another patient (e.g., unopened vials, containers, and unit-dose packages). If this definition is not clarified it will affect the accuracy of estimates for many questions, including question A-13 and A-14, where the distinction between unused pharmaceuticals that are disposed versus unused pharmaceuticals that can be returned to stock or re-dispensed is important.

Related to the definition of unused pharmaceuticals, does the EPA wish to collect data about disposal of partial fill or empty vials, such as those used in the preparation of chemotherapy? Trace pharmaceutical wastes are mentioned in Table A-2 but it is unclear if trace amounts of pharmaceutical wastes should be reported. If so, this intent should be clarified in the definition and explained in the survey instructions. Investigational drug products are also handled as hazardous wastes. Is data collection about those products also desired? Does the EPA also wish to collect data about the disposal of unused patient-specific extemporaneously-prepared intravenous admixtures?

Within Part D, the questionnaire should include a clear definition of hazardous wastes. It is important to note that current definitions offered by the EPA, NIOSH, DoT, state regulatory agencies, and professional associations, such as ASHP can differ significantly.

For question A-11, the first answer option should read "med room **or cart**" to be inclusive of all non-technology based storage approaches. Consider adding "locked storage in patient room" as another answer option. For this same question, Table A-1 should instruct survey respondents to check all that apply because responsibility for drug transfer is frequently shared by more than one individual for the steps that are defined in the table. In addition, pharmacy technicians serve a critical role in these processes. It may be useful to include these individuals as a distinct category of personnel, or expand the existing category to "pharmacists **or pharmacy technicians.**"

Regarding question A-12, ASHP believes it will be difficult or impossible for facilities to provide accurate estimates of the number of doses administered. While accurate dispensing records exist, the number of doses dispensed can differ dramatically from the number of doses actually administered. Electronic medication administration records (eMARs) represent actual administration, but use of eMARs is not common to all facilities. Therefore, the number of billed dosages is recommended as a more accurate and retrievable estimate of drug product use.

Also for question A-12, the unit of measure for topical products or bulk oral liquid medications (e.g., cyclosporin solution) should be “packages” or “units,” rather than “doses.” A similar approach to packages or units billed is recommended. For all components of question A-12, the Society asks the EPA to clarify the rationale for requesting information by dosing formulation. The burden of collecting these data is high and the Society questions whether it would provide useful information.

Question A-13 offers similar challenges for accurate measurement of returned or un-administered doses. In addition, the word “administered” is confusing because the question asks for unused or excess doses, which by definition would not be administered. “Dispensed” would be a more appropriate word choice.

Question A-14 requests a percent breakdown for reasons why drug products are not used with all reasons expected to total 100% of wastes. It is unlikely that facilities could provide accurate estimates for each reason using retrospective data. A prospective approach would be needed to provide reliable data.

For question A-15, in the second answer option, include “pharmacy staff” among those trained to determine disposal requirements.

In questions A-15 through A-17 and elsewhere in the survey, ASHP encourages the EPA to refrain from including specific names of proprietary services or products (e.g., EcoRx, PharmE Waste Wizard).

Question A-18 requests a percent breakdown for management practices for specific types of pharmaceutical waste products. Again, it is unlikely that facilities could provide accurate estimates for each reason using retrospective data. In addition, the rationale that practices will add up to 100% is not correct. For example, all hazardous drug products may be returned to the pharmacy, which may in turn use reverse distribution for all, or a portion, of these products. The resultant calculation would exceed 100%. The option of “reused” should also be included if ASHP’s recommendation to clarify unused but undisposed (i.e., re-used) products is not addressed,

For Question A-20 in Table A-3, estimating the time specific personnel spend in the disposal of wastes via various practices will be difficult to measure either retrospectively or prospectively, and is unlikely to provide useful information.

Also in Table A-3, the categories for average monthly costs should delineate time spent in preparing unused products for shipment to the reverse distributor as well as service fees charged by that company. Note that while costs for disposal of chemotherapy, biohazard, and RCRA containers should be readily available, costs associated with disposal by drain or general waste are difficult to quantify. ASHP recommends that the questions on costs and personnel time allocation be split into two distinct questions.

For Question A-21, does the EPA plan to collect information for all drug products in Attachment B? Facilities do not maintain records for all of these specific drug products and would not be able to provide retrospective data on their disposal. In addition, ASHP questions whether data collection is needed for this extensive list of products and recommends that data be collected prospectively for antibiotics, antivirals, drugs requiring special disposal according to state regulations that govern pharmaceutical waste disposal, and the DoT, EPA, and DEA. While some have recommended assessing disposal of hazardous drugs defined by NIOSH's hazardous drug list, it should be noted that this list is intended as an example. NIOSH states that it is current only through the date of publication and recommends that facilities maintain facility-specific lists. In addition, the table is unnecessarily cumbersome because it requires facilities to add product classification and designate whether the product is hazardous, chemotherapy, or a controlled substance. This information is known and should be pre-populated on the form to ease the burden on facilities.

Data generated from questions A-22, A-23, and A-27 would be more instructive if respondents were asked to identify specific drug classes or products that are disposed by drain. This data would highlight areas where education is needed.

For question A-25, ASHP recommends adding the following answer option, "as wastes are generated." This option will assess disposal that occurs when products are made incorrectly or contaminated during preparation or administration (e.g., dropped tablets discarded in general trash.)

For Question A-26, it is unclear how the first option, "use of an automatic dispensing system," would reduce pharmaceutical wastes. Options that should be added include "batch preparation of products in standardized concentrations" and "unit-of-use packages." These strategies minimize wastage and contribute significantly to pollution prevention activities.

Question A-27 should include "reverse distribution," "disposal via medical or biohazard containers," and "disposal via trash for incineration" as options for non-drain disposal.

For Part B, see comments in previous section, Extent of Burden on Facilities and Suggested Strategies for Implementation.

For Part C, the survey must include a specific area where facilities can document that the data was collected prospectively. This is essential because ASHP believes that most facilities will need to use this approach to provide accurate information.

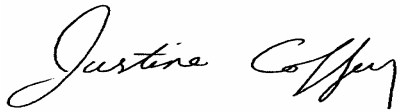
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ASHP appreciates this opportunity to present its written comments pertaining to the draft questionnaire. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs